REMARKS

Applicants respectfully request reconsideration of this application in view of the foregoing amendments and the following remarks.

I. Introductory Remarks

Upon entry of the foregoing amendments, claims 10, 23-24 and 26-29 will be pending in the application. Claims 11-12 and 25 are being canceled. Claims 28-29 are being added. Claims 10, 24 and 26 are being amended. Exemplary support for the claim amendments exists in original claims 11-12 and in the specification at page 17, lines 13-18 and at page 51, line 17 through page 52, line 2.

II. The Claims Comply with the Written Description Requirement

Claims 10-12 and 23-27 were rejected for allegedly failing to comply with the written description requirement of 35 U.S.C. § 112, first paragraph. In particular, the Office stated that the claims "encompass significant structural dissimilarity and diversity as compared to the ALK-7 protein (SEQ ID NO: 2)" and that the specification does not describe a representative number of ALK-7 polypeptides. Applicants respectfully traverse the rejection.

The claimed ALK-7 polypeptides are unified by significant structural similarity to the full-length ALK-7 protein. As recited in claim 10, the polypeptides must (a) have the full length amino acid sequence of SEQ ID NO: 2, (b) have an amino acid sequence that is at least 95% identical to that of SEQ ID NO: 2, (c) have the catalytic domain encoded by amino acid residues 193-485 of SEQ ID NO: 2 or (d) have the cytoplasmic domain encoded by amino acids 137-493 of SEQ ID NO: 2. Describing biomolecules by reference to a defining sequence or partial sequence is appropriate when the sequence/structure correlates with common functional characteristics. In this case, a polypeptide meeting the structural requirements of (a), (c) or (d) set forth above will have an intact ALK-7 catalytic domain, and would therefore be expected to have kinase activity. A polypeptide meeting the requirement of (b) set forth above will have an essentially intact ALK-7 catalytic domain, and would therefore be expected to have kinase activity.

Contrary to the rejection, therefore, the claims do not "encompass significant structural dissimilarity and diversity as compared to the ALK-7 protein," and the disclosed species are representative of the entire claimed genus. Accordingly, Applicants request withdrawal of the written description rejection.

III. The Claims Comply with the Enablement Requirement

Claims 10-12 and 23-27 were rejected for allegedly failing to comply with the enablement requirement of 35 U.S.C. § 112, first paragraph. In particular the Office stated that although the specification is enabling for the complete ALK-7 protein, KA-tagged ALK-7, ALK-7DN, and ALK-7TD proteins, it does not provide evidence that other ALK-7 variants, fragments, domains or polypeptides "perform a function for neuron growth or survival." Applicants respectfully traverse the rejection.

The Office failed to meet is burden for lodging an enablement rejection. In order to make a rejection the Office bears an initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). "[I]t is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure." *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). Additionally, the Office bears a burden of explaining why *no* disclosed use of the invention is enabled. If *any* use is enabled when multiple uses are disclosed, the application is enabling of the claimed invention.

In this case, the Office did not provide a reasonable basis for doubting that the claimed ALK-7 polypeptides are functional. The Office merely cited a paper indicating that the substitution of a single amino acid in fibroblast growth factor can lead to a substantial loss of heparin binding, receptor binding and biological activity for that protein. However, many substitutions, deletions and insertions have no impact on protein function, particularly

conservative substitutions or substitutions at positions that are not involved in protein folding. This explains the existence of many naturally occurring protein variants across species and allelic variants within a single species. Indeed, proteins must tolerate minor variation in order to survive during the course of evolution. Moreover, artisans routinely predict protein function based on similarity to other proteins. The enablement rejection therefore relies on an exceptional circumstance in which a single point mutation adversely affects protein function. Such an exceptional circumstance is not a reasonable basis for questioning the enablement of this invention.

Additionally, even if the claimed polypeptides lacked kinase activity, they still have a substantial practical use. ALK-7 is expressed in restricted regions of the brain, notably the hippocampus, hypothalamic nuclei, substantia nigra and pituitary. (*See*, specification, Example 3). Thus, the claimed ALK-7 polypeptides are useful for identifying ligands that can be used as biopharmaceuticals to promote the growth and survival of neurons. (*See*, specification, p.31). Additionally, the claimed ALK-7 polypeptides are useful for producing antibodies, which can specifically target therapeutic and diagnostic agents to the hippocampus, hypothalamic nuclei, substantia nigra and pituitary and identify cells from those tissues in a broader population of cells. (*See*, specification pp. 53-54).

Because the claimed polypeptides are useful, and because the Office has not met its burden of showing otherwise, Applicants respectfully request withdrawal of the enablement rejection.

IV. The Claims Are Patentable over the Cited Art

Claims 10-12 and 24-25 were rejected as allegedly being anticipated by Ibanez et al., (US Patent No: 5614609). According to the Office, Ibanez disclosed a protein consisting of an amino acid sequence that is 94.2% identical to that of SEQ ID NO: 2. Applicants respectfully traverse the rejection.

The protein of Ibanez does not meet the claimed invention's limitations. More particularly, the protein of Ibanez does not have the full length amino acid sequence of SEQ ID NO: 2, does not have an amino acid sequence that is at least 95% identical to that of SEQ

ID NO: 2, does not have the catalytic domain encoded by amino acid residues 193-485 of SEQ ID NO: 2, and does not have the cytoplasmic domain encoded by amino acids 137-493 of SEQ ID NO: 2. Because Ibanez does not describe a protein meeting each and every limitation of the claims, it does not anticipate the claims. Accordingly, Applicants request withdrawal of the anticipation rejection.

V. Concluding Remarks

This application is now in condition for allowance, and Applicants respectfully request favorable reconsideration of it.

If the Examiner believes that an interview would advance prosecution of the application or help to clarify issues pertaining to prosecution, he or she is invited to contact the undersigned attorney by telephone.

The Commissioner is hereby authorized to charge any additional fees that may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorize payment of any extension fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 9/6/05

By Todd Smalley #55,638 for

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5475
Facsimile: (202) 672-5399

Beth A. Burrous
Attorney for Applicant
Registration No. 35,087